

## REMARKS

Reconsideration of the rejections based upon the foregoing amendments and the following remarks is respectfully requested.

### **A. Allowable Subject Matter**

Applicants would like to thank the Examiner for indicating that claims 18 and 20 contain allowable subject matter.

### **B. Claims 1 and 4-7 were rejected under 35 U.S.C. §102(b) as being anticipated by Blackmer (US 3,661,748).**

Claim 1 specifically requires the steps of “a) applying a signal having an AC component to the sensor; b) measuring an AC response to the signal; and c) using the AC response to determine if the sensor is abused.” It is respectfully submitted that the cited reference does not teach or suggest the above-recited elements of Applicants’ claim 1.

The Office Action alleges that Blackmer teaches a “system for detecting a sensor fault” that meets the above recited elements of Applicants’ claim 1 (Office Action, paragraph 2). However, Applicants’ claim 1 specifically claims a method “to determine if the sensor is abused.” The term “abused” has been specifically defined in Applicant’s specification as follows:

In order to provide an extra measure of quality control to the analyte measurement process, particularly when the test system is to be used by a non-professional end user, it is desirable to detect sensors (test strips) that have been mis-dosed (double dosed, etc.), that have been previously used, or that have degraded enzymes (from being stored in too humid an environment, being too old, etc.). These conditions are collectively referred to as “abused sensors.” It is desired to devise a test that

will abort the analyte measurement process (or at least warn the user that the test results may not be accurate) if an abused sensor is inserted into the test meter.  
(Page 43, first paragraph)

The “sensor fault” being detected by the application of an AC signal in Blackmer consists of either 1) detecting a leakage of ions through a damaged membrane 30, 32 (col. 2, line 64 through col. 3, line 4), or 2) detecting poor contact between an electrode and the solution, or that the electrode has been completely removed from the solution (col. 3, lines 4-13). None of these faults meets the definition of “abused sensor” as given in Applicants’ specification. It is therefore respectfully submitted that Blackmer does not teach or suggest Applicants’ claimed “using the AC response to determine if the sensor is abused.” Therefore, it is believed that claim 1 is allowable over the references of record.

Claims 4-7 depend from claim 1 and therefore include all of the limitations of claim 1. It is therefore respectfully submitted that claims 4-7 are allowable over the references of record for at least the same reasons set forth above with respect to claim 1.

**C. Claims 1-17, 19 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over White (US 5,352,351) in view of Blackmer.**

Claim 1 specifically requires the steps of “a) applying a signal having an AC component to the sensor; b) measuring an AC response to the signal; and c) using the AC response to determine if the sensor is abused.” It is respectfully submitted that the cited references do not teach or suggest the above-recited elements of Applicants’ claim 1.

The Office Action alleges that it “would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the failsafe procedure of White to incorporate the AC fault measurements of Blackmer because of the ability to detect faulty sensors in a variety of formats as taught by Blackmer” (Office Action, p.4, first full paragraph).

As conceded in the Office Action, White does not teach the use of signals having an AC component. The Office Action attempts to cure this deficiency by combining White with Blackmer, who teaches "the ability to detect faulty sensors" using AC signals. However, Applicants' claim 1 specifically claims a method including the step of "using the AC response to determine if the sensor is abused." The term "abused" has been specifically defined in Applicant's specification as follows:

In order to provide an extra measure of quality control to the analyte measurement process, particularly when the test system is to be used by a non-professional end user, it is desirable to detect sensors (test strips) that have been mis-dosed (double dosed, etc.), that have been previously used, or that have degraded enzymes (from being stored in too humid an environment, being too old, etc.). These conditions are collectively referred to as "abused sensors." It is desired to devise a test that will abort the analyte measurement process (or at least warn the user that the test results may not be accurate) if an abused sensor is inserted into the test meter.  
(Page 43, first paragraph)

The "sensor fault" being detected by the application of an AC signal in Blackmer consists of either 1) detecting a leakage of ions through a damaged membrane 30, 32 (col. 2, line 64 through col. 3, line 4), or 2) detecting poor contact between an electrode and the solution, or that the electrode has been completely removed from the solution (col. 3, lines 4-13). None of these faults meets the definition of "abused sensor" as given in Applicants' specification. It is therefore respectfully submitted that Blackmer does not teach or suggest Applicants' claimed "using the AC response to determine if the sensor is abused" and the combination of White and Blackmer therefore can not make this claimed element obvious. Therefore, it is believed that claim 1 is allowable over the references of record.

Claims 2-7 depend from claim 1 and therefore include all of the limitations of claim 1. It is therefore respectfully submitted that claims 2-7 are allowable over the references of record for at least the same reasons set forth above with respect to claim 1.

Similarly, Applicants' claim 8 specifically requires "combining the normalized Cottrell Failsafe Ratio and the AC response to produce an indication of whether the sensor has been abused." For the same reasons set forth above with respect to claim 1, it is respectfully submitted that claim 8 is allowable in view of the references of record.

Claims 9-17 depend from claim 1 and therefore include all of the limitations of claim 8. It is therefore respectfully submitted that claims 9-17 are allowable over the references of record for at least the same reasons set forth above with respect to claim 8.

Claim 19 specifically requires "determining a failure condition indicating an abused sensor in a blood glucose concentration test, comprising the steps of: a) applying a first test signal having an AC component to a test sample; ...and e) determining a failure condition value based upon the first phase angle response the second phase angle response and a predetermined Cottrell Failsafe Ratio." For the same reasons set forth above with respect to claim 1, it is respectfully submitted that claim 19 is allowable in view of the references of record. Furthermore, neither the White nor Blackmer references teach or suggest, alone or in combination, the use of AC phase angle measurements in combination with a Cottrell Failsafe Ratio in order to determine if a sensor is abused. For all of these reasons, it is respectfully submitted that claim 19 is allowable in view of the references of record.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance, and respectfully request such action. Applicants respectfully request that the Examiner telephone the undersigned attorney for Applicants at 317-634-3456 if the Examiner does not find that all claims are in condition for allowance as presented herein.

Respectfully submitted,

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